## REMARKS

Claims 1-9, 13, 18, and 30-44 are pending in the application. Claims 30, 38, 43, and 44 are amended from the previous versions. Claims 1-9, 13, and 33-37 are allowed, and claim 32 is allowable.

This pending application is a reissue continuation of 09/776,394, which is a reissue application of U.S. Patent No. 5,865,846.

Contents of Reissue Application

The Office Action objects to the original disclosure of the reissue patent application. The Office Action indicates that the Applicants must "substitute the originally filed claims, specification, drawings, etc.., with the corrected claims, drawings and specification and the newly amended claims." Pg. 3.

With a supplemental response filed on May 17, 2007, Applicants submitted the Specification and claims of U.S. Patent No. 5,865,846 in double column format, of which this application is a continuation reissue application, and Applicants submitted a copy of the drawings. Nevertheless, in order to ensure the application continues to move forward, by this response, Applicants are resubmitting a copy of each of these documents. Accordingly, as attachments to this paper, Applicants submit

1) Specification and claims of U.S. Patent No. 5,865,846 in double column format, of which this application is a continuation reissue application; and
2) Drawings.

Cross-reference to parent reissue application 09/776,394

The Office Action states that the application must be amended to include a reference to parent reissue application 09/776,394. By this paper, Applicants submit such an amendment to the specification. Note that the Applicants submitted the continuation (albeit without the dual column patent format) with this reference already in place. Because the original specification should have been in the double column format however, Applicants submit this amendment to amend the dual column format version of the application.

Reissue Oath/Declaration

The Office Action indicates that the reissue oath/declaration is defective because it fails to contain the correct language and that a new declaration must be filed before the application can be allowed. When the Patent Office indicates that all the pending claims are in condition for allowance, Applicants will file the supplemental oath.

Ownership Interest

As an attachment to this paper, Applicants are filing a new Consent of Assignee and ownership statements. In a telephone conversation with the Examiner on August 27, 2007, the Examiner stated that the current owner, Warsaw Orthopedic, should be the entity that signs the Consent of Assignee. Accordingly, the ownership attachments include:

1) Written Consent of Assignee (PTO/SB/53); and

2) Statement Under 37 C.F.R. 3.73(b) (PTO/SB/96).

Applicants request that the Examiner review and enter these papers.

Allowable Subject Matter

Applicants acknowledge the indication that claims 1-9, 13, and 33-37 are allowed, with claim 32 being allowable.

Claims

The Office Action indicates that the claims stand rejected as being based upon a defective oath or declaration. Pg. 4. It also indicates that receipt of an appropriate supplemental oath will overcome the rejection. As stated above, Applicants will file the supplemental oath when all the claims are in a condition for allowance.

Claims 18, 30, 38, 39, and 43 are rejected under §102(b) as being anticipated by, or under §103 as being obvious in view of U.S. Patent No. 4,863,477 to Monson.

Claims 18, 30, 38, 39, and 43 are rejected under §102(b) as being anticipated by U.S. Patent No. 4,863,477 to Bainville et al.

Claims 31, 40-42, and 44 are rejected under §103 as being unpatentable over Monson.

By this paper, Applicants are amending claims 30, 38, 43, and 44. In the claim listing, these claims are provided in proper form for a reissue application. However, for the convenience of the Examiner, these claims are reproduced below to show the changes introduced in this paper.

30. (Currently amended) A method of surgery comprising:

removing at least a portion of a natural spinal disc from between confronting vertebral bodies,

forming partially hemispherical surfaces in endplates of the confronting vertebral bodies, the partially hemispherical surfaces being different from a natural surface of the endplates; and

inserting between the formed partially hemispherical surfaces an intervertebral disc prosthesis comprising confronting supports, each support having a partially hemispherical exterior surface adapted to mate with one of the formed partially hemispherical surfaces, wherein the supports are capable of movement relative to each other after the prosthesis has been inserted between the formed partially hemispherical surfaces.

38. (Currently amended) A method of surgery comprising:

forming a first artificial surface in a [[an]] natural endplate of a first vertebral body, the first artificial surface being arcuate in multiple planes and having a shape different than the shape of the natural endplate;

inserting a motion-preserving disc prosthesis into an intervertebral space adjacent to the formed first arcuate surface; and

positioning a first portion of the inserted prosthesis against the formed first surface of the first vertebral body, wherein the first portion has an exterior configuration adapted to mate with the formed first surface.

43. (Currently amended) A method of surgery comprising:

removing a spinal disc between confronting vertebral bodies;

forming concave surfaces in the natural endplates of the confronting vertebral bodies that have a shape different than the shape of the natural endplates, and

inserting between the formed concave surfaces an intervertebral disc endoprosthesis, comprising:

(1) confronting concaval-convex supports, each support having an exterior convex surface adapted to mate with one of the formed concave surfaces, and

(2) a resilient body element interposed between the concaval-convex supports.

44. (Currently amended) A method of endoprosthetic discectomy surgery comprising:

receiving information about the size, shape and nature of a patient's involved natural spinal vertebral bodies and natural spinal vertebral discs from imaging devices,

removing at least the involved, damaged natural spinal disc material from the patient's spine,

forming concave surfaces in adjacent natural spinal vertebral bodies, the concave surfaces being concave about multiple planes and having a shape different than the shape of the natural vertebral bodies, and

implanting an intervertebral disc endoprosthesis comprising a resilient disc body and concaval-convex elements at least partly surrounding the resilient disc body in the patient's spine.

Support for these claim amendments can be found in the original issued patent at column 6, lines 44-67.

Claim 18

The Office Action indicates that claim 18 is rejected as being anticipated or obvious in view of Monson and anticipated by Bainville. Applicants traverse these rejections. Claim 18 requires, among other steps, "implanting at least one anchor in an anterior surface of at least one of confronting vertebral bodies." Neither Monson nor Bainville disclose any method including this feature. Each of Monson and Bainville discloses intervertebal disc prostheses that are implanted within the intervertebral space. These may disclose implantation through an anterior approach. However, this is still not implanting an anchor "in an anterior surface" of a vertebral body. There is no disclosure in either patent that discloses or that suggests implanting an anchor in an anterior surface of one of the vertebral bodies. The Office Action identified the projections on the Monson device as being the claimed anchor and identified the relatively flat outer surfaces on the Bainville device as being the claimed anchor. Neither of these, however, come into contact with an anterior surface of the vertebral bodies. Accordingly, Applicants respectfully request that these rejections be withdrawn and that claim 18 be indicated as allowable.

Applicants note that in a prior Office Action, claim 18 (formerly numbered as claim 9) was indicated as allowable.

Claim 30

Applicants submit that claim 30 is not anticipated nor obvious in view of Monson and not anticipated by Bainville. Claim 30 recites, among other things,

> removing at least a portion of a natural spinal disc from between confronting vertebral bodies;

forming partially hemispherical surfaces in endplates of the confronting vertebral bodies, the partially hemispherical surfaces being different from a natural surface of the endplates.

Neither Monson nor Bainville disclose all these features. Monson, in relevant part, states "At the point of implantation, following excision and removal of a damaged natural disc and its surrounding annulus . . . ." Col. 5, lines 30-31. It discloses removal of the disc. The Office Action states "It is an inherent characteristic of the method of replacing artificial discs to use tools in order to remove the damage material in the disc." The claim recites, however, "forming . . . surfaces in endplates" and that the formed surfaces are "different from a natural surface of the endplates." The prior art identified may include removing the damaged discs, but they do not include shaping of the endplates. Even removing the damaged disc with tools does not anticipate the forming of surfaces that are different than the natural surfaces of the endplates.

Like Monson, Bainville also does not anticipate claim 30. Bainville states, "the disk prosthesis 7 in overall manner reproduces the shape of the intervertebral disk which it replaces." However, claim 30 is directed to a method where the endplate surfaces are modified from their original natural shape. Instead, in the claimed method, the partially hemispherical surfaces formed in the endplates are "different from a natural surface of the endplates." While Bainville may disclose removal of the damaged disc and implanting a prosthetic disk, it does not disclose forming surfaces in the end plates "different from a natural surface of the endplates."

To even more particularly distinguish claim 30 from the cited references, by this paper Applicants have amended claim 30 to recited the step of removing at least a portion of the natural spinal disc. This limitation is added to further clarify that forming the partially hemispherical surfaces in endplates is more than or in addition to "removing at least a portion of the natural disc." Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim 38

Applicants submit that claim 38 is not anticipated nor obvious in view of Monson and not anticipated by Bainville. Claim 38 recites, among other things:

> forming a first artificial surface in a natural endplate of a first vertebral body, the first artificial surface being arcuate in multiple planes and having a shape different than the shape of the natural endplate

Neither Monson nor Bainville disclose all these features. Monson, in relevant part, states "At the point of implantation, following excision and removal of a damaged natural disc and its surrounding annulus . . . ." Col. 5, lines 30-31. It discloses removal of the disc. The Office Action states "It is an inherent characteristic of the method of replacing artificial discs to use tools in order to remove the damage material in the disc." The claim recites, however, "forming a first artificial surface in a natural endplate" and that the first artificial surface has "a shape different than the shape of the natural endplate." The prior art references identified may include removing the damaged discs, but they do not include shaping of the endplates to form a surface different than the shape of the natural endplate. Even removing the damaged disc with tools does not anticipate the forming of a surface having a shape different than the shape of the natural endplate.

Like Monson, Bainville also does not anticipate claim 38. Bainville states, "the disk prosthesis 7 in overall manner reproduces the shape of the intervertebral disk which it replaces." However, claim 38 is directed to a method where the endplate surfaces are modified from their original natural shape. Instead, in the claimed method, the arcuate surface formed in the endplates is "different from a natural surface of the endplates." While Bainville may disclose removal of the damaged disc and implanting a prosthetic disk, it does not disclose forming surfaces in the end plates "having a shape different than the shape of the natural endplate."

Accordingly, Applicants respectfully request that the rejection be withdrawn and the claim be allowed.

Claim 41

Claim 41 stands rejected under 35 U.S.C. §103 as being obvious in view of Monson. Claim 41 recites, among other things:

> forming a first artificial surface in a natural endplate of a first vertebral body, the first artificial surface being arcuate in multiple planes and having a shape different than the shape of the natural endplate.

In order for a rejection to be upheld under 35 U.S.C. §103, the prior art must teach all the claimed elements. Here, Monson neither teaches nor suggests at least the step of "forming a first artificial surface in a natural endplate" that has "a shape different than the shape of the natural endplate." Monson, in relevant part, states "At the point of implantation, following excision and removal of a damaged natural disc and its surrounding annulus . . . ." Col. 5, lines 30-31. It discloses removal of the disc. This is not a suggestion of modifying the endplate of the vertebral body. If anything, it suggests that the vertebral body endplate is not modified. There is no teaching or suggesting that it is forming a shape different than the shape of the natural endplate. Monson does not disclose modifying the shape of the endplate by forming a first artificial surface having a shaped different than the shape of the natural endplate.

The Office Action indicates that the recitation of a milling jig is obvious. However, the claim recites, "attaching a milling jig to a vertebral body" and "milling an endplate" in the recited manner. This is not obvious based on the Monson teachings. Even if using a tool to remove a disc were obvious, as suggested in the Office Action, there is not suggestion or teaching of attaching a milling jig to a vertebral body and no suggestion of using any tool to form the *endplate* (as opposed to the natural disc) to have the relative shape and sizes claimed.

Accordingly, Applicants respectfully request that the Examiner properly consider all the elements of the claim and pass it to allowance.

Claim 43

Applicants submit that claim 43 is not anticipated nor obvious in view of Monson and not anticipated by Bainville. Claim 43 recites, among other things:

> forming concave surfaces in the natural endplates of the confronting vertebral bodies that have a shape different than the shape of the natural endplates.

Neither Monson nor Bainville disclose all these features. Monson, in relevant part, states "At the point of implantation, following excision and removal of a damaged natural disc and its surrounding

annulus . . . ." Col. 5, lines 30-31. It discloses removal of the disc. The Office Action states "It is an inherent characteristic of the method of replacing artificial discs to use tools in order to remove the damage material in the disc." The claim recites, however, "forming concave surfaces in the natural endplates . . . that have a shape different than the shape of the natural endplates." The prior art references identified may include removing the damaged discs, but they do not include shaping of the endplates to form a surface different than the shape of the natural endplate. Even removing the damaged disc with tools does not anticipate the forming of a surface having a shape different than the shape of the natural endplate.

Like Monson, Bainville also does not anticipate claim 43. Bainville states, "the disk prosthesis 7 in overall manner reproduces the shape of the intervertebral disk which it replaces." However, claim 43 is directed to a method where the endplate surfaces are modified from their original natural shape. Instead, in the claimed method, the concave surfaces formed in the endplates are "different than the shape of the natural endplates." While Bainville may disclose removal of the damaged disc and implanting a prosthetic disk, it does not disclose forming concave surfaces in the natural endplates that have a shape different than the shape of the natural endplates."

Accordingly, Applicants respectfully request that the rejection be withdrawn and the claim be allowed.

Claim 44

Claim 44 stands rejected under 35 U.S.C. §103 as being obvious in view of Monson. Claim 44 recites, among other things:

> forming concave surfaces in adjacent natural spinal vertebral bodies, the concave surfaces being concave about multiple planes and having a shape different than the shape of the natural vertebral bodies

In order for a rejection to be upheld under 35 U.S.C. §103, the prior art must teach all the claimed elements. Here, Monson neither teaches nor suggests at least the step of "forming concave surfaces in adjacent natural spinal vertebral bodies" that has "a shape different than the shape of the natural vertebral bodies." Monson, in relevant part, states "At the point of implantation, following excision and removal of a damaged natural disc and its surrounding annulus . . . ." Col. 5, lines 30-31.

It discloses removal of the disc. This is not a suggestion of modifying the endplate of the vertebral body. If anything, it suggests that the vertebral body endplate is not modified. There is no teaching or suggesting that it is forming a shape different than the shape of the natural vertebral body. Monson does not disclose modifying the shape of the vertebral body by forming concave surfaces in adjacent natural spinal vertebral bodies that have "a shape different than the shape of the natural vertebral bodies."

Accordingly, Applicants respectfully request that the rejection be withdrawn and the claim be allowed.

Dependent Claims

Each of the dependent claims also are believed to be distinct from the art of record, for example for the same reasons discussed above with respect to their associated independent claim. Accordingly, Applicants respectfully request that the Examiner withdraw the rejections and allow these claims.

Conclusion

As a result of the foregoing, it is respectfully asserted that pending claims 1-9, 13, 18, and 30-44 are in condition for allowance.

The Final Office Action contains characterizations of the claims and the related art to which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Final Office Action.

If the Examiner believes a telephone conversation would be useful for advancing prosecution of this application, she is invited to telephone the undersigned at 972-739-6969.

No fees, including extension of time fees, are believed necessary for consideration of the present paper. If any fees, including claim fees and extension of time fees, are necessary for the proper submission of this paper, the extension of time is hereby requested, and the Commissioner is hereby authorized to charge any fees, including claim fees and those for the extension of time, to Haynes and Boone, LLP's Deposit Account No. 08-1394.

Respectfully submitted,

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I hereby certify that this correspondence is being filed with the U.S. Patent and Trademark Office via EFS-Web on September 5, 2007.

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# HUMAN SPINAL DISC PROSTHESIS

This is a divisional of U.S. patent application Ser. No. 08/681,230, filed Jul. 22, 1996, U.S. Pat. No. 5,674,296, and which is a continuation-in-part of U.S. patent application Ser. No. 08/339,490, filed Nov. 14, 1994, which is abandoned.

## BACKGROUND OF THE INVENTION

This invention relates generally to human prostheses, and especially to spinal column vertebral disc prostheses. The invention also relates to surgical procedures for preparing the patient to receive a vertebral disc endoprosthesis, and for implanting that endoprosthesis in the patient's spine.

The herniation of a spinal disc and the often resultant symptoms of intractable pain, weakness, sensory loss, incontinence and progressive arthritis are among the most common of debilitating processes affecting mankind. If a patient's condition does not improve after conservative treatment, and if clear physical evidence of nerve root or spinal cord compression is apparent, and if correlating radiographic studies (i.e., MRI or CT imaging or myelography) confirm the condition, surgical removal of the herniated disc may be indicated. The process of discectomy—as the name implies—involves the simple removal of the disc without attempt to replace or repair the malfunctioning unit. In the United States in 1985, over 250,000 such operations were performed in the lumbar spine and in the cervical spine.

Statistics suggest that present surgical techniques are likely to result in short-term relief, but will not prevent the progressive deterioration of the patient's condition in the long run. Through better pre-operative procedures and diagnostic studies, long-term patient results have improved somewhat. But it has become clear that unless the removed disc is replaced or the spine is otherwise properly supported, further degeneration of the patient's condition will almost certainly occur.

In the mid-1950's and 60's, Cloward and Smith & Robinson popularized anterior surgical approaches to the cervical spine for the treatment of cervical degenerative disc disease and related disorders of the vertebrae, spinal cord and nerve root; these surgeries involved disc removal followed by interbody fusion with a bone graft. It was noted by Robinson (Robinson, R.A.: The Results of Anterior Interbody Fusion of the Cervical Spine, J. Bone Joint Surg., 440A: 1569–1586, 1962) that after surgical fusion, osteophyte (bone spur) reabsorption at the fused segment might take place. However, it has become increasingly apparent that unfused vertebral segments at the levels above and below the fused segment degenerate at accelerated rates as a direct result of this fusion. This has led some surgeons to perform discectomy alone, without fusion, by a posterior approach in the neck of some patients. However, as has occurred in surgeries involving the lower back where discectomy without fusion is more common as the initial treatment for disc herniation syndromes, progressive degeneration at the level of disc excision is the rule rather than the exception. Premature degenerative disc disease at the level above and below the excised disc can and does occur.

Spine surgery occasionally involves fusion of the spine segments. In addition to the problems created by disc herniation, traumatic, malignant, infectious and degenerative syndromes of the spine can be treated by fusion. Other procedures can include bone grafts and heavy duty metallic rods, hooks, plates and screws being appended to the



patient's anatomy; often they are rigidly and internally fixed. None provide for a patient's return to near-normal functioning. Though these procedures may solve a short-term problem, they can cause other, longer term, problems.

A number of attempts have been made to solve some of the problems described above by providing a patient with spinal disc prostheses, or artificial discs of one sort or another. For example, Steffee, U.S. Pat. No. 5,031,437, describes a spinal disc prosthesis having upper and lower rigid flat plates and a flat elastomeric core sandwiched between the plates. Frey et al., U.S. Pat. Nos. 4,917,704 and 4,955,908, disclose intervertebral prostheses, but the prostheses are described as solid bodies.

U.S. Pat. Nos. 4,911,718 and 5,171,281 disclose resilient disc spacers, but no inter-connective or containing planes or like elements are suggested, and sealing the entire unit is not taught.

It is the primary aim of the present invention to provide a vertebral disc endoprosthesis which will perform effectively and efficiently within a patient's spine over a long period of time, and which will not encourage degeneration of or cause damage to adjacent natural disc parts.

It is another object to provide a vertebral disc endoprosthesis which does not require pins or other common mechanical hinge elements, yet which permits natural motion of the prosthetic parts and the adjacent natural anatomy.

It is a related objective to provide a new vertebral disc endoprosthesis surgical procedure which will decrease post-operative recovery time and inhibit post-operative disc, vertebral body and spinal joint degeneration.

It is yet another object to provide a method of installing the endoprosthesis so as to accurately mate the endoprosthesis with an adjacent specifically formed bone surface. An associated object is to provide an endoprosthesis which will encourage bone attachment to, and growth upon, adjacent outer surfaces of the endoprosthesis.

Yet another object is to provide a vertebral endoprosthesis in which the parts are non-oncogenic.

Still another object is to provide a vertebral disc endoprosthesis having a resilient element to accommodate shocks and other forces applied to the spine.

Another object is to provide a highly effective vertebral endoprosthesis which includes several disc endoprostheses and one or more prosthetic vertebral bodies. A related object is to provide these elements in a pre-assembled array for implantation in a patient.

## SUMMARY OF THE INVENTION

To accomplish these objects, the invention comprises a resilient body formed of a material varying in stiffness from a relatively stiff exterior portion to a relatively supple central portion. A concaval-convex means at least partly surrounds that resilient body so as to retain the resilient body between adjacent vertebral bodies of a patient's spine. If medical considerations so indicate, several disc endoprostheses can be combined with one or more endoprosthetic vertebral bodies in an entire assembly.

To implant this endoprosthesis assembly, information is obtained regarding the size, shape, and nature of a patient's damaged natural spinal discs. If one or more of the patient's vertebral bodies also require replacement, information about those bodies is also obtained. Thereafter, one or more prosthetic disc units and interposed prosthetic vertebral body units are constructed and preassembled in conformity with

that information. Finally, the completed and conformed prosthetic disc and vertebral body assembly is implanted in the patient's spine.

Other objects and advantages of the invention will become apparent upon reading the following detailed description and upon reference to the drawings. Throughout the drawings, like reference numerals refer to like parts.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a fragmentary vertical view of a portion of a human spine in which is installed a novel vertebral disc endoprosthesis embodying the present invention;

FIG. **2** is a fragmentary side elevational view similar to FIG. **1** showing the elements of a patient's spine and having a novel vertebral disc endoprosthesis embodying the present invention installed therein;

FIG. **3** is a sectional view taken substantially in the plane of line **3—3** in FIG. **1**;

FIG. **4** is an exploded view of the novel vertebral disc endoprosthesis;

FIG. **5** is a vertical fragmentary view of a patient's spine similar to FIG. **1**, but showing a series of novel disc endoprosthesis units installed in the spine and interconnected to one another;

FIG. **6** is a fragmentary sectional view of a patient's spine similar to FIG. **3** and taken along line **6—6** in FIG. **5**, but showing a natural upper vertebral body, and upper endoprosthetic disc; an adjacent endoprosthetic vertebral body; a second or lower endoprosthetic disc; and a second or lower natural vertebral body; p FIG. **7** is a sectional view taken substantially in the plane of line **7—7** of FIG. **6**;

FIG. **8** is a fragmentary side elevational view of the assembly shown in FIG. **6**; and

FIG. **9** is a fragment vertical view, similar to FIG. **1**, of a portion of a human spine in which is installed a variant form of the novel vertebral disc endoprosthesis the variant form having a prosthetic longitudinal ligament;

FIG. **10** is a sectional view taken substantially in the plane of line **10—10** in FIG. **9**;

FIG. **11** is a top view of a retainer means for use with a vertebral disc endoprosthesis;

FIG. **12** is a sectional view taken substantially in the plane of line **12—12** of FIG. **11**;

FIG. **13** is a side view of a vertebral disc endoprosthesis having a groove for receiving the retainer means; and

FIG. **14** is a cross-sectional view of the retainer means in use.

## DETAILED DESCRIPTION

While the invention will be described in connection with a preferred embodiment and procedure, it will be understood that it is not intended to limit the invention to this embodiment or procedure. On the contrary, it is intended to cover all alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

Turning more specifically to FIGS. **1–3**, a portion of a human spine **10** is shown. The illustrated spine **10** has been subjected to a discectomy surgical process. To discourage degeneration of or damage to the natural vertebral bodies **12** and **14** and their respective facet joints, in accordance with the invention, a vertebral disc endoprosthesis **18** is affixed between the adjacent natural vertebral bodies **12** and **14**. Here this vertebral disc endoprosthesis **18** comprises a resilient disc body **20** having a relatively stiff annular gasket exterior portion **22** and a relatively supple nuclear central portion **24**. The annular gasket **22** can be formed from a suitable biocompatible elastomer of approximately 90 durometer hardness and the nuclear central portion **24** can be formed from a softer biocompatible elastomeric polymer of approximately 30 durometer hardness.

Concaval-convex means **30** surround the resilient body **20** to retain the resilient body **20** between the adjacent natural vertebral bodies **12, 14** in a patient's spine **10**. To this end, as shown in FIG. **3**, the concaval-convex means **30** comprise two generally L-shaped supports **32** and **34**. The supports **32, 34** each have confronting first concaval-convex legs **42, 44**, each leg being of relatively constant cross-sectional thickness. Each leg **42, 44** has an outer convex surface **52, 54** for engaging the adjacent bone of the natural vertebral bodies **12, 14**. Corresponding inner concave surfaces **62, 64** in confronting array retain the resilient body **20** in its illustrated compressive force shock-absorbing position. These supports **32** and **34** can undergo principle movement away from one another, but only limited secondary translational, rotational and distractional motion will occur. Each support **32, 34** has a second wing or leg **72, 74** extending generally perpendicularly to the first legs **42, 44** respectively, and adapted for affixation to the adjacent bone structure. To carry out aspects of the invention described below, this affixation is effectively accomplished by cannulated screw devices **82, 84** which may be of a biodegradable type manufactured by Zimmer of Largo, Fla. Each device **82, 84** comprises a screw **92, 94**; and a screw anchor **102, 104** adapted to threadably receive the screw extends radially into and seats within the bone structure **12, 14** as especially shown in FIG. **3**.

To discourage and prohibit migration of fluids between the endoprosthesis **18** and adjacent parts of the anatomy, a seal member **110** is attached to the supports **32, 34** so as to surround the resilient body **20** comprised of the gasket **22** and nucleus **24**, in accordance with another aspect of the invention. Here, this seal member **110** comprises a flexible sheet material having a multiplicity of pores. Preferably, the pores are from about 5 microns to about 60 microns in size. A flexible, strong polymer sheet material from which this seal is formed can be a Kevlar-like material, or it can be Goretex-like material, or other appropriate biocompatible material, such as polyether, polyurethane, or polycarbonate urethane membranes, can be used. Kevlar material is offered by the E. I. DuPont de Nemours Company of Wilmington, Delaware and Goretex material is offered by the W. T. Gore Company of Flagstaff and Phoenix, Arizona. Known sealing material can be applied to the flexible sheet material so as to render the flexible sheet material substantially impervious to the passage of any fluid. A watertight seal is perfected when the seal **110** is glued or otherwise affixed to the legs **42, 44** and mediate portions of the legs **72, 74** as suggested in FIGS. **1—3**.

In an alternative embodiment, the watertight seal between the endoprosthesis **18** and adjacent parts of the anatomy can be provided by developing a groove **402** completely encircling the periphery of each of the legs **42, 44**. Only one of the grooves is shown in FIG. **13**. In this embodiment, the seal member **410** is provided with a beaded edge **412** for each groove. Additionally, a retaining band **415** is provided for each groove to retain the seal member **410** in grooves **402**. The retaining bands **415** can be in the form of a biocompatible monofilament wire of, for example, stainless steel or titanium, a synthetic polymer cable or a braided wire cable. As shown in FIG. **11**, each retaining band is crimped anteriorly by a crimping sleeve **420**. Of course, more than

one crimping sleeve may be used, if necessary. Although one sealing arrangement consisting of the groove, beaded edge and retaining band is shown in FIG. **14**, it should be understood that the sealing arrangement on the concaval-convex leg of the other support is identical in design and function.

In use, the seal member **410** is placed about the concaval-convex means **30**. The retaining bands **415** are then placed adjacent to the respective groove **402** and crimped anteriorly, thereby fitting the bands into the grooves. Each beaded edge **412** prevents the slipping of the seal member underneath the retaining band. Thus, the retaining band, the groove and the beaded edge all cooperate to provide a water-tight seal to prevent the migration of fluids between the endoprosthesis **18** and adjacent parts of the anatomy. Glue can also be used to affix the seal member to the concaval-convex means **30** as a supplemental means for perfecting the seal.

In accordance with another aspect of the invention, the supports **32, 34** are formed of a biocompatible metal which may contain chromium cobalt or titanium. Surface roughening or titanium beading **112, 114** on the exterior surfaces **52, 54** of legs **42, 44** encourages positive bonding between the adjacent bone and the convex surfaces **52, 54**.

As suggested in FIGS. **9** and **10**, a prosthetic longitudinal ligament **250** can be connected between the screws **92, 94** to limit motions between elements of the spine **10** in the area where the endoprosthesis **18** is implanted. This strap **250** may be made of the Kevlar-like material or the Goretex-like material described above, or it may be made of any other strong biocompatible material.

In accordance with another aspect of the invention, multiple endoprosthetic disc units can be placed in series with a straddling interlock appendage providing stability and fixation as shown in FIG. **5**. Entire portions of a patient's spine can be replaced by a series of interconnected endoprosthetic vertebral bodies and endoprosthetic disc units. FIGS. **6–8** show an upper natural vertebral body unit **312** to which an upper endoprosthetic body **308** has been attached. A lower natural vertebral body **314** has attached, at its upper end, an endoprosthetic disc unit **318**. Between these endoprosthetic disc units **308** and **318** is an endoprosthetic vertebral body **320**. As suggested by FIG. **7**, the endoprosthetic vertebral body **320** need not be irregularly shaped in cross sectional aspect; rather, manufacturing processes may suggest that it have a circular cross-sectional shape. As show in FIGS. **6** and **8**, this endoprosthetic vertebral body **320** comprises a titanium element **321**, to which are attached the preformed upper and lower endoprosthetic vertebral body upper and lower concaval-convex elements **322, 324**. Each concaval-convex element **322, 324** is attached to the prosthetic vertebral body **320**, as shown in FIG. **7**, by extending set screws **330** through the titanium vertebral body **321** into a stem-like projection **331** extending from each of the concaval-convex elements **322, 324**. A hole **360** in the body **320** accommodates the stem-like projections **331** of the concaval-convex elements **322** and **324**. The stem-like projection **331** of the concaval-convex elements **322** and **324** is used only in conjunction with a prosthetic vertebral body implant construction **320**.

An ear **340** is affixed, as by weldments **341**, to a leg **342** extending from a concaval-convex element **322** as illustrated in FIGS. **6** and **8**. An anchor **352** can be threaded into the endoprosthetic vertebral body **320**, and a screw **362** can be turned into the anchor **352** so as to rigidly assemble the leg **342** to a leg **354** extending from the lower endoprosthetic disc unit **318**.

The upper disc endoprosthesis **308**, the endoprosthetic vertebral body **320**, and the lower disc endoprosthesis **318** can all be assembled and interconnected as a unit before implantation in a patient's body when indicated.

As also suggested in FIG. **6**, the annular corners **372, 374** of natural vertebral bodies **312, 314** each can extend irregularly radially outwardly of the adjacent disc endoprosthesis **308, 318**. However, the comers **382B, 384B** of the prosthetic vertebral body **320** do not generally extend significantly outside those disc units **308, 318**, thus discouraging vertebral body engagement with and consequent abrasion or other damage to adjacent portions of the patient's natural anatomy. Preferably the endoprosthetic vertebral body **320** is not exactly right cylindrical in shape, but is rather slightly biconical; that is, the endoprosthetic vertebral body **320** has a waist **390** of minimum radius R at an axial medial point as suggested in FIG. **6**.

According to yet another aspect of the invention, novel surgical procedures permit effective and permanent installation of the endoprosthetic vertebral body **320** and associated parts. First, a surgeon or medical technician develops information about the size, shape and nature of a patient's damaged vertebral body or bodies from radiographs, CT and/or MRI scans, noting specifically the anterior-posterior and lateral dimensions of the end plate of each involved vertebral body and the vertical height of the anterior aspect of each involved vertebral and/or proximate vertebral body and vertical height of the mid portion of involved and proximate relatively normal intervertebral disc spaces. This information is transmitted by telephone, computer datalink or documentary transport to a specialized laboratory. That laboratory constructs one or more prosthetic assemblies of the sort shown in FIG. **6** in conformity with the received information and this disclosure. Each of the assemblies can include a prosthetic vertebral body **321**, and at each body end is a prosthetic disc **308,318**. Each prosthetic disc unit comprises, in turn, the concaval-convex elements **30**; the resilient body **20** interposed between the concaval-convex elements; and the seal unit **110** secured around the interior legs and resilient body. Thereafter, the completed and conformed assembly is implanted in the patient's spine **10**.

When the unit or units have been received and the patient properly prepared, the damaged natural spinal disc or discs and vertebral body or bodies are removed and the adjacent spinal bone surfaces are milled or otherwise formed to provide concave surfaces to receive the confronting convex surfaces **52, 54**. Thereafter, the disc units and vertebral body are installed in the patient's spine.

To accurately locate the concaval-convex surfaces in the patient's spine, holes **382A, 384A** (FIG. **3**) are precisely located and then formed in the bone structure using a measuring instrument centered in the evacuated natural intravertebral disc space. These holes are then tapped to form female threads therein. When the threads have been formed, the anchors **102, 104** are implanted in the respective tapped holes, thereby creating reference points located precisely with respect to the patient's spine. After the holes have been formed and the anchors **102, 104** implanted, a bone surface milling jig (not shown) is affixed to the anchors **102, 104** and the desired concave surfaces of predetermined shape are formed on the inferior and superior surfaces of the opposing vertebral bodies using one of a selection of predetermined milling head or bit sizes. Thereafter, the bone milling jig is removed and the concaval-convex elements **52, 54** identical in shape to the milled surfaces **112, 114** are inserted between the distracted milled vertebral bodies **12, 14**. The distraction device is then moved. The concaval-

convex structures are then attached by the same anchors **102**, **104** to the bone, thus insuring a precise and stable mate between the bone surfaces and the convex surfaces **52**, **54**.

If necessary, a damaged implanted nucleus and/or gasket **24** can be removed and replaced. This can be accomplished by slitting the seal **110**; removing the annular gasket **24** and damaged nucleus **22**, and replacing them with new, undamaged elements. Thereafter, the seal **110** can be re-established by suturing or gluing closed the slit seal.

We claim:

**1**. A method of endoprosthetic discectomy surgery comprising the steps of receiving information about the size, shape and nature of a patient's damaged natural spinal vertebral bodies and discs from radiographs, CT and/or MRI scans or other imaging devices specifically determining the anterior-posterior and lateral dimensions of each involved vertebral body, the vertical height of the anterior aspect of each involved vertebral and/or proximate vertebral body, and the vertical height of the mid-portion of the involved and proximate normal intervertebral disc spaces, thereafter constructing one or more prosthetic vertebral body units and prosthetic disc units in conformity with the received information, each prosthetic disc unit including confronting L-shaped concaval-convex elements and a resilient body interposed between the concaval-convex elements; and an endoprosthetic vertebral body interposed between and engaging the adjacent disc units; and thereafter implanting the completed and conformed construction in the patient's spine.

**2**. A method according to claim **1** including the step of constructing a plurality of prosthetic disc units and further including the step of attaching the disc units to an endoprosthetic vertebral body prior to the step of supplying the assembly to the surgeon.

**3**. A method according to claim **1** further including the steps of surgically milling spinal bone surfaces with concave surfaces to receive confronting convex surfaces of the concaval-convex elements, and installing at least one disc unit having concaval-convex elements with said convex surfaces in the patient's spine.

**4**. A method of surgery comprising the steps of removing a vertebral disc from a patient's spine, forming holes at precisely predetermined locations in bone structure adjacent the location of the removed disc, tapping the holes to form a female thread in each hole, and threadably implanting an anchor into each tapped hole, thereby creating reference points located precisely with respect to the patient's spine, forming concave surfaces in adjacent spinal bone, and inserting between the formed bone surfaces a vertebral disc endoprosthesis including confronting concaval-convex supports, each support having an exterior convex surface adapted to mate with the adjacent formed concave spinal bone surface, the endoprosthesis further including a resilient body element interposed between the concaval-convex supports, and thereafter affixing the concaval-convex supports to the adjacent bone.

**5**. A method of surgery according to claim **4** further including the step of temporarily locating a bone surface milling jig at the site of the removed vertebral disc by means of said anchors prior to implanting said disc endoprosthesis.

**6**. A method of surgery according to claim **4** further including the steps of attaching a screw to each concaval-convex support and screwing said screw into the implanted anchor.

**7**. A method of surgery according to claim **4** further comprising the steps of identifying a damaged resilient nucleus body element or annular gasket in an implanted endoprosthesis, removing said damaged nucleus body element or annular gasket from the endoprosthesis and inserting a new, undamaged nucleus body element or annular gasket into the endoprosthesis without removing the concaval-convex supports from the patient's spine.

**8**. A method of spinal surgery comprising the steps of forming mounting holes in one or more vertebral bodies of a patient's spine; utilizing said mounting holes to mount a bone mill on a patient's spine; milling confronting bone surfaces on and in the patient's spine to a predetermined surface shape; removing said mill; and thereafter mounting a vertebral disc endoprosthesis having a predetermined outer surface shape by means of the original mounting holes so that outer surfaces of the vertebral disc endoprosthesis mate precisely with the previously milled bone surfaces.

**9**. A method of endoprosthetic discectomy surgery comprising the steps of receiving information about the size, shape and nature of a patient's involved and proximate normal natural spinal vertebral bodies and natural spinal vertebral discs from known imaging devices, thereafter constructing at least one vertebral disc endoprosthesis comprising a resilient disc body and concaval-convex elements at least partly surrounding the resilient disc body, removing at least the involved, natural spinal discs from the patient's spine, forming concave surfaces in adjacent spinal bone, and thereafter implanting the vertebral disc endoprosthesis in the patient's spine.

* * * * *

FIG. 1

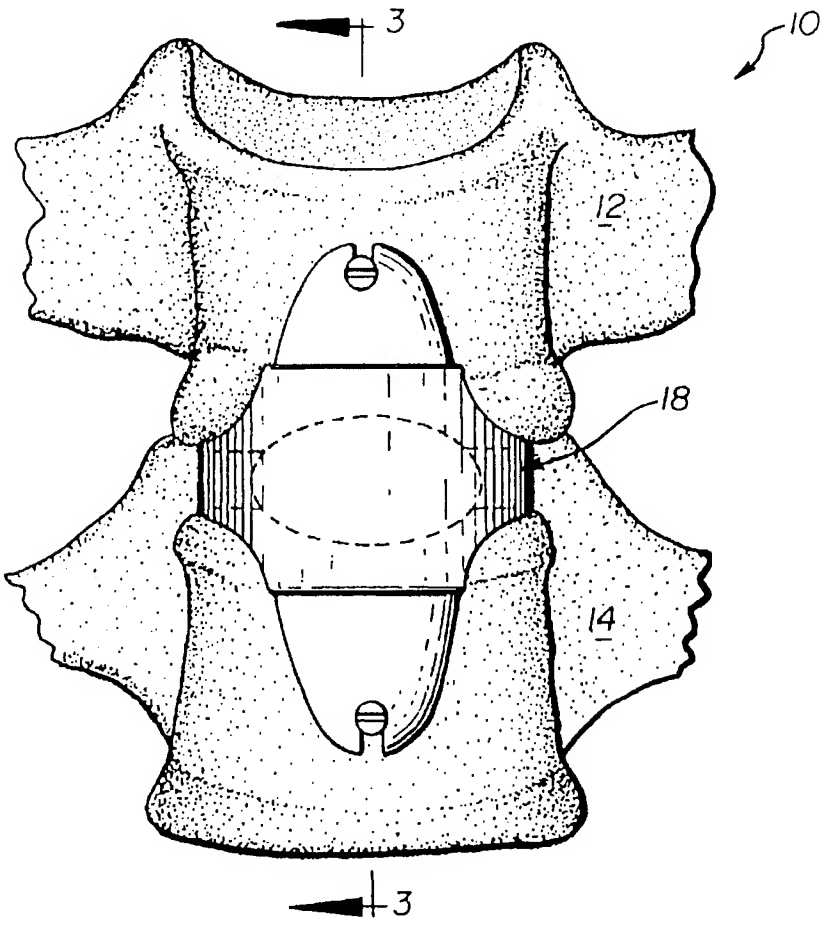


FIG. 2

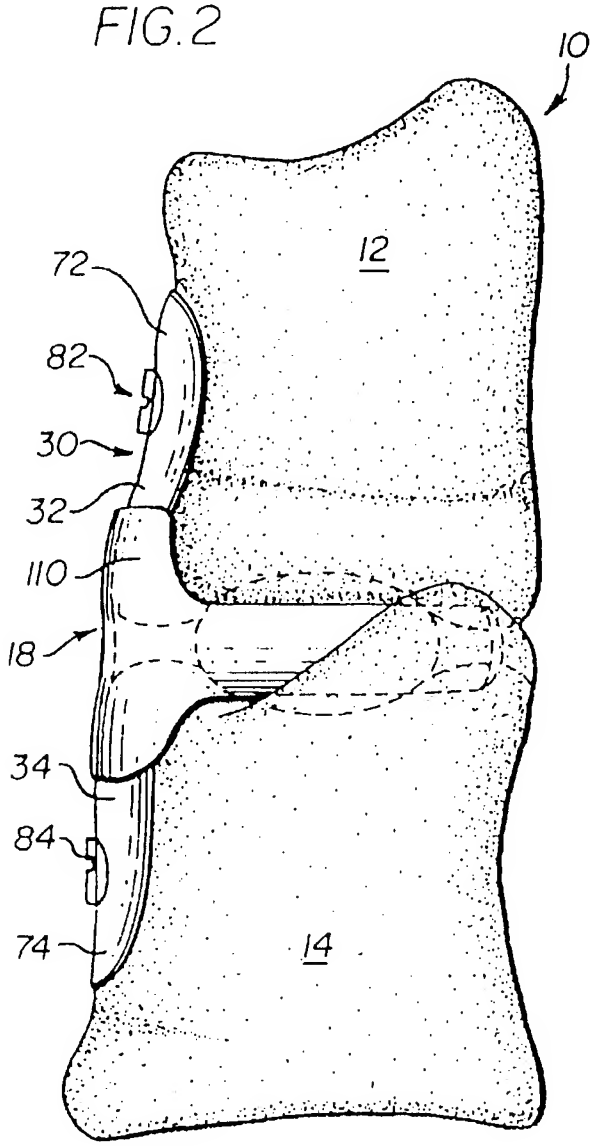
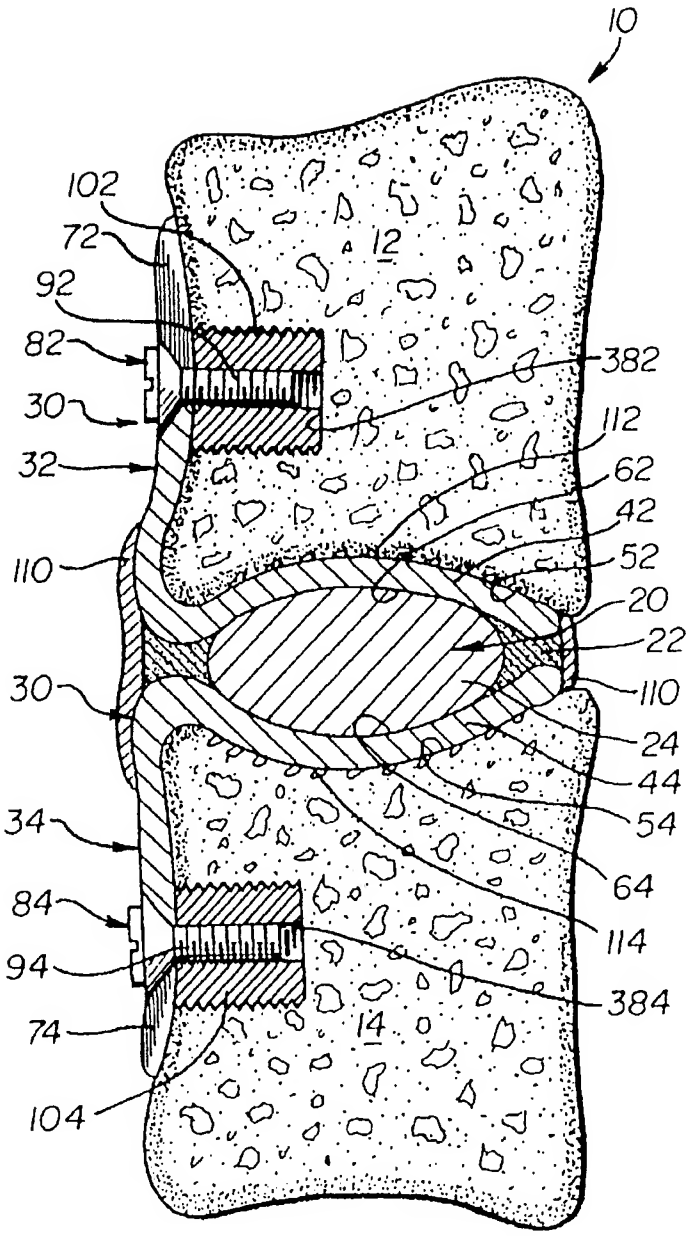


FIG. 3


10
102
72
12
92
82
382
30
112
32
62
42
52
110
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22
30
110
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44
54
34
64
84
114
94
384
74
14
104

FIG. 4

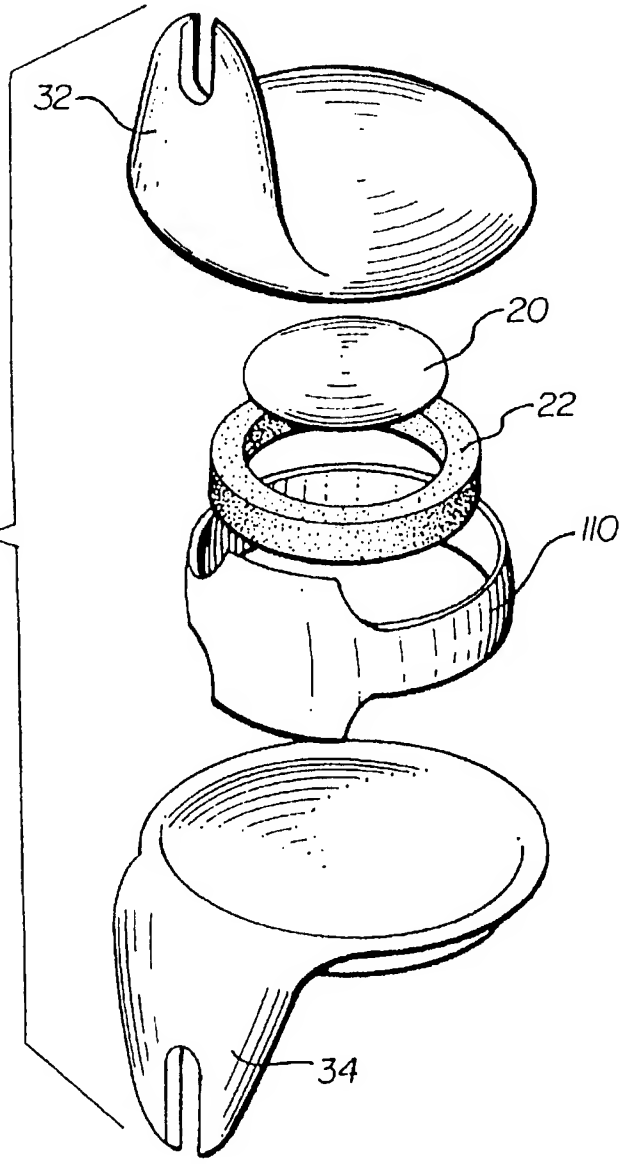


FIG. 5

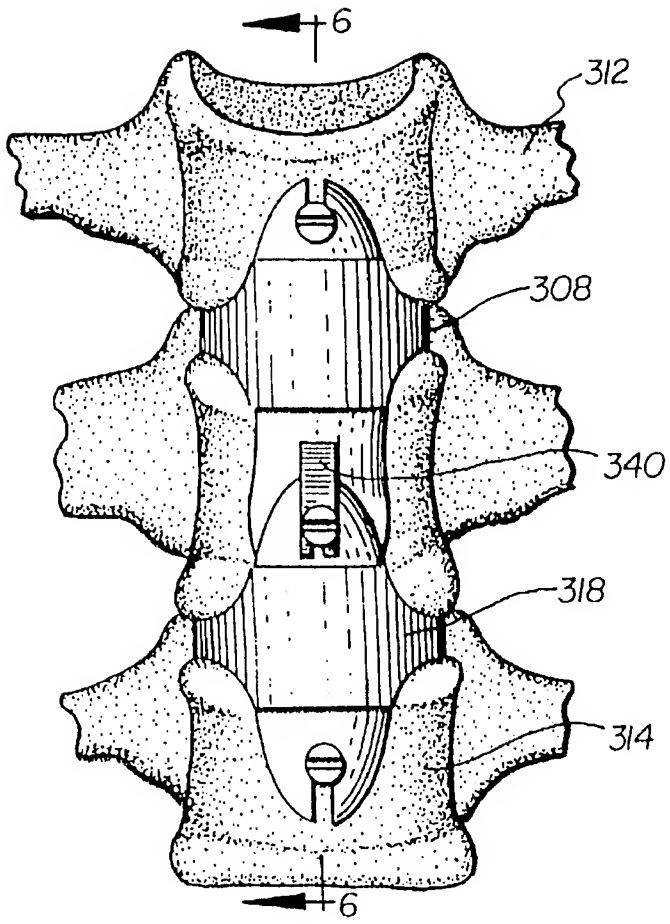


FIG.6

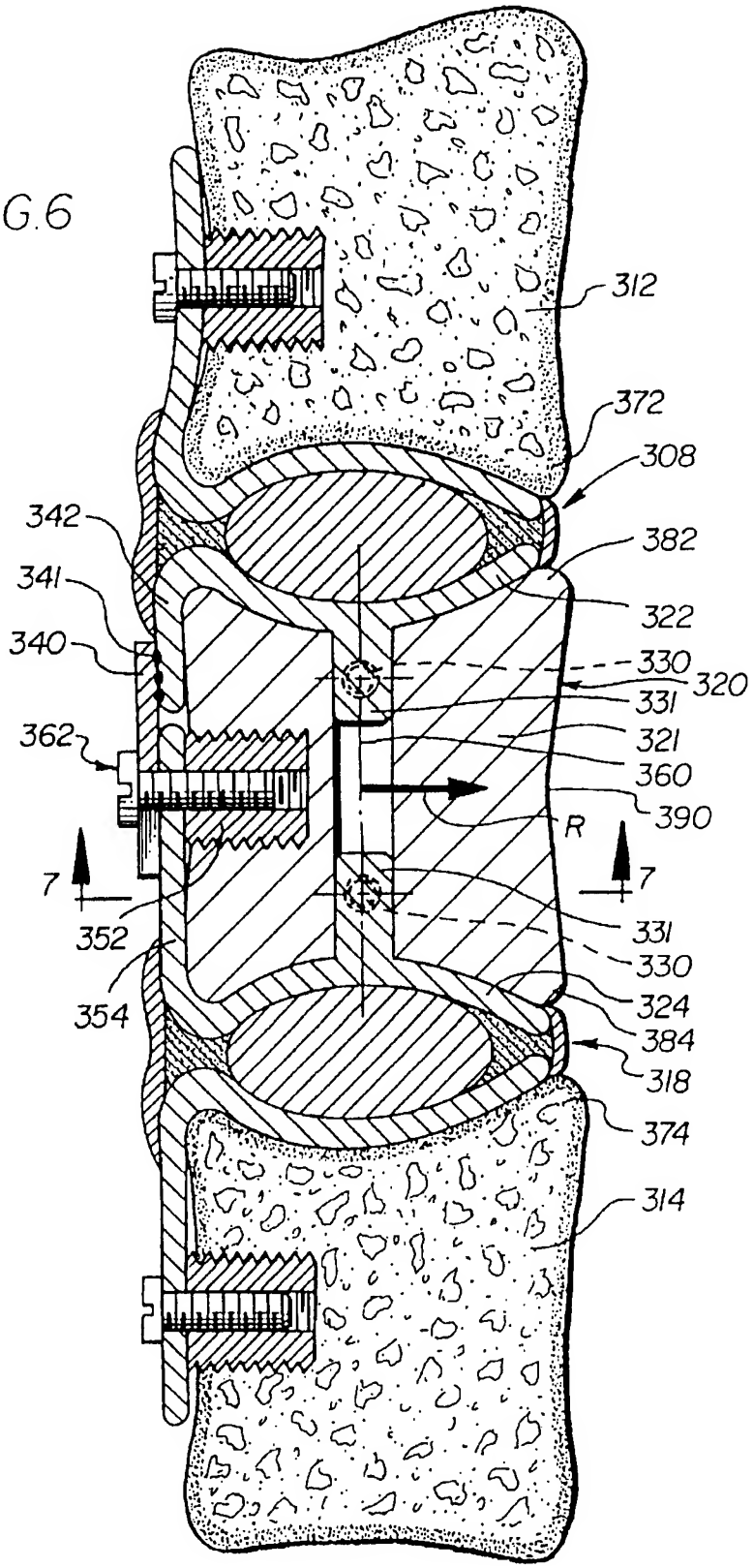

312
372
308
342
382
341
322
340
330
320
331
362
321
360
390
R
7
7
352
331
330
354
324
384
318
374
314

FIG. 7

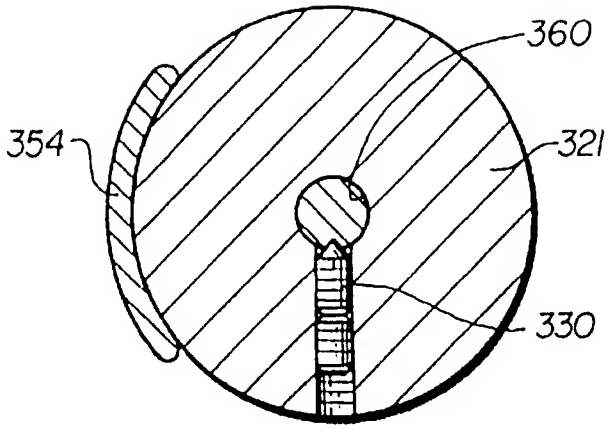



FIG. 8

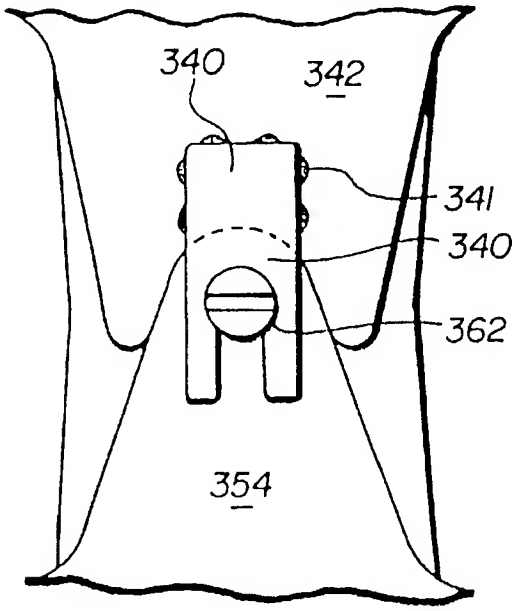


FIG. 9

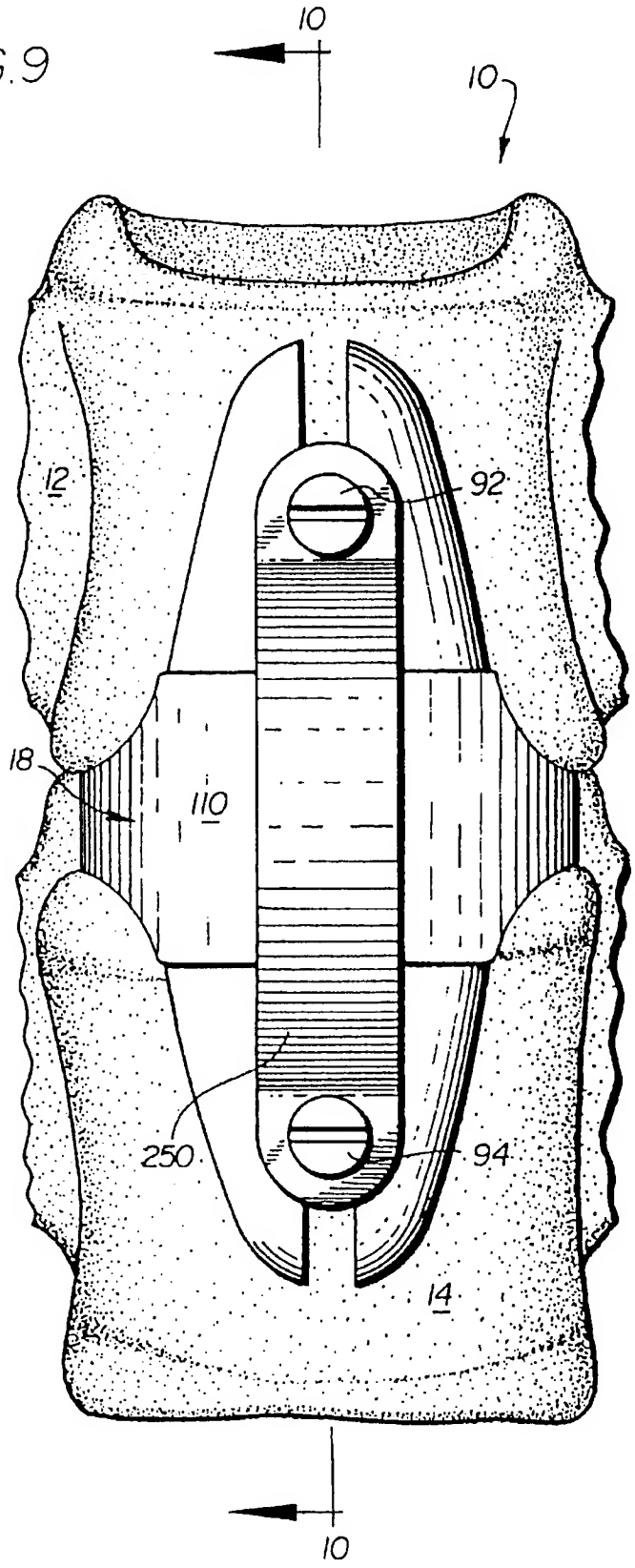


FIG. 10

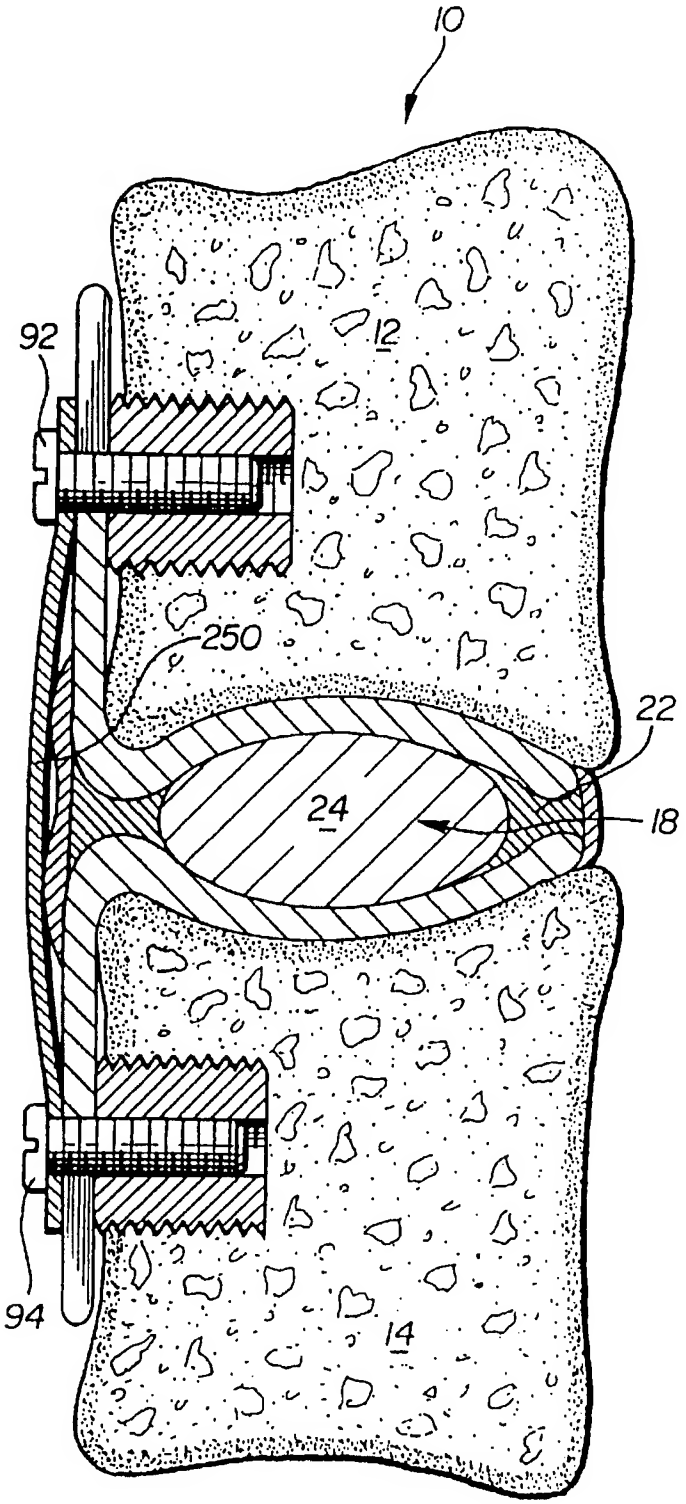


FIG. 11

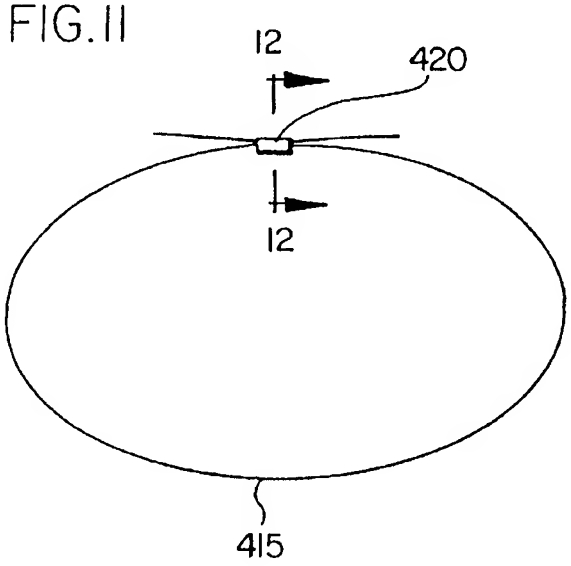



FIG. 12

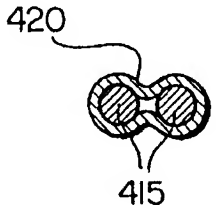



FIG. 13

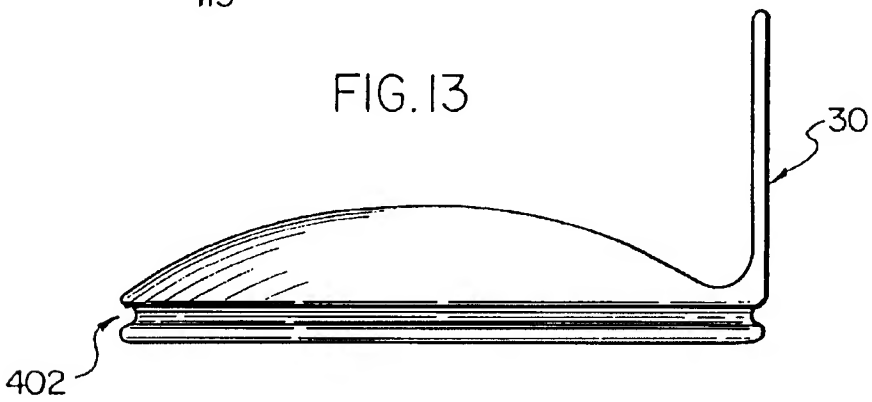
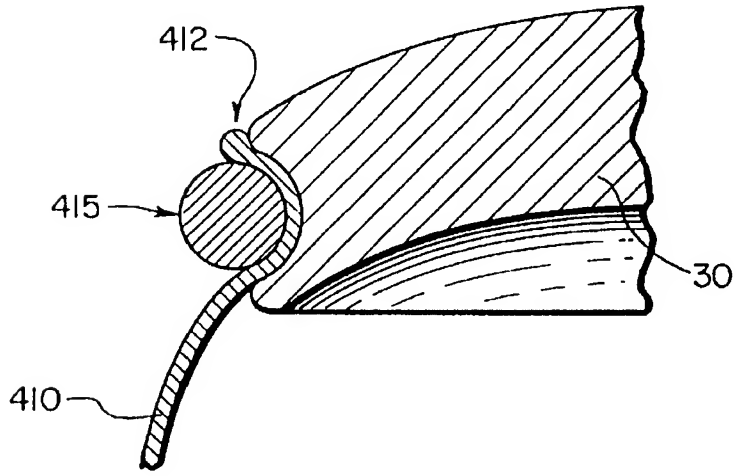



FIG. 14



PTO/SB/53 (08-07)
Approved for use through 08/31/2007. OMB 0651-0033
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE


| REISSUE APPLICATION: CONSENT OF ASSIGNEE; STATEMENT OF NON-ASSIGNMENT | Docket Number (Optional) 31132.189 |
|---|---|

This is part of the application for a reissue patent based on the original patent identified below.

Name of Patentee(s)
Vincent Bryan and Alex Kunzler

| Patent Number | Date Patent Issued |
|---|---|
| 5,865,846 | February 2, 1999 |

Title of Invention

1. [X] Filed herein is a statement under 37 CFR 3.73(b). (Form PTO/SB/96)

2. [ ] Ownership of the patent is in the inventor(s), and no assignment of the patent is in effect.

One of boxes 1 or 2 above must be checked. If multiple assignees, complete this form for each assignee. If box 2 is checked, skip the next entry and go directly to "Name of Assignee".

The written consent of all assignees and inventors owning an undivided interest in the original patent is included in this application for reissue.

The assignee(s) owning an undivided interest in said original patent is/are Warsaw Orthopedic, Inc. and the assignee(s) consents to the accompanying application for reissue. No. 10/713,837

Name of assignee/inventor (if not assigned) Warsaw Orthopedic, Inc.

| Signature | Date |
|---|---|
| Noreen Johnson | August 30, 2007 |

Typed or printed name and title of person signing for assignee (if assigned)

Noreen Johnson,
Vice President

PTO/SB/96 (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE


# STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Warsaw Orthopedic, Inc.

Application No./Patent No.: 10/713,837 Filed/Issue Date: November 14, 2003

Entitled: Human Spinal Disc Prosthesis

Warsaw Orthopedic, Inc., a corporation
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☑ the assignee of the entire right, title, and interest; or

2. ☐ an assignee of less than the entire right, title and interest
(The extent (by percentage) of its ownership interest is _____ %)

in the patent application/patent identified above by virtue of either:

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

B. ☑ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: Vincent Bryan and Alex Kunzler To: Spinal Technologies Corporation
The document was recorded in the United States Patent and Trademark Office at
Reel 008591, Frame 0468, or for which a copy thereof is attached.

2. From: Spinal Technologies Corporation To: Spinal Dynamics Corporation
The document was recorded in the United States Patent and Trademark Office at
Reel 008513, Frame 0981, or for which a copy thereof is attached.

3. From: Spinal Dynamics Corporation To: Medtronic Sofamor Danek, Inc.
The document was recorded in the United States Patent and Trademark Office at
Reel 013669, Frame 0543, or for which a copy thereof is attached.

☑ Additional documents in the chain of title are listed on a supplemental sheet.

☐ As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (*i.e.*, a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Noreen C. Johnson — Aug 30, 2007
Signature — Date

Noreen C. Johnson — (901) 399-2228 x6228
Printed or Typed Name — Telephone Number

Vice President
Title

PTO/SB/96 (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE


Supplemental Sheet

## STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Warsaw Orthopedic, Inc.

Application No./Patent No.: 10/713,837 Filed/Issue Date: November 14, 2003

Entitled: Human Spinal Disc Prosthesis

Warsaw Orthopedic, Inc., a corporation
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☑ the assignee of the entire right, title, and interest; or

2. ☐ an assignee of less than the entire right, title and interest
(The extent (by percentage) of its ownership interest is _____ %)

in the patent application/patent identified above by virtue of either:

A. ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

B. ☑ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: Medtronic Sofamor Danek, Inc. To: SDGI Holdings, Inc.
The document was recorded in the United States Patent and Trademark Office at
Reel 015635, Frame 0232, or for which a copy thereof is attached.

2. From: SDGI Holdings, Inc. To: Warsaw Orthopedic, Inc.
The document was recorded in the United States Patent and Trademark Office at
Reel 019084, Frame 0771, or for which a copy thereof is attached.

3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☐ As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

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The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

Noreen C. Johnson — 8/30/07

Signature — Date

Noreen C. Johnson — (901) 399-2228 x6228

Printed or Typed Name — Telephone Number

Vice President

Title